

Appl. No. 09/652,493  
Amdt. Dated December 17, 2004  
Reply to Office action of May 18, 2004

- c. providing a normal value for  $\alpha$ -dystroglycan expression levels on cell surfaces; and
- d. comparing the detection levels of  $\alpha$ -dystroglycan to said normal value, whereby the absence a decrease in levels of  $\alpha$ -dystroglycan on said cells of the sample indicates a higher potential for tumorigenicity.

**Claim 6 (Currently amended):** The method of claim 5, wherein said detecting comprises:

- a. adding to said sample a monoclonal antibody specific for  $\alpha$ -dystroglycan, and
- b. measuring the amount of labeled  $\alpha$ -dystroglycan detected.

**Claim 7 (Original):** The method of claim 5, wherein said cells are human mammary epithelial cells.

**Claim 8 (Currently amended):** The method of claim 5, wherein the step of providing a normal value comprises measuring said detecting comprises measurement of the amount of  $\alpha$ -dystroglycan relative to the amount of  $\beta$ -dystroglycan on the surface of said cells, wherein a relative decrease in the ratio of  $\alpha$ -dystroglycan to  $\beta$ -dystroglycan indicates  $\alpha$ -dystroglycan shedding and higher potential tumorigenicity.

**Claims 9 – 21 (Canceled).**

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**Claim 22 (Currently amended):** A method of determining the likelihood that a patient has a tumor, by assaying proteolysed  $\alpha$ -dystroglycan fragments shed from a cell into blood in patient serum, said method comprising the steps of:

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- a. contacting a serum sample to be assayed with a labeled antibody specific for an  $\alpha$ -dystroglycan fragment, and
- b. assaying the amount of bound label,  
whereby wherein said  $\alpha$ -dystroglycan fragments bound to said labeled antibody are is positively correlated with existence of a tumor cell growth in the patient.

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Claim 23 (Currently amended): The method of Claim 22, wherein the  $\alpha$ -dystroglycan fragment is an a fragment of approximately 120 kD fragment.

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Claim 24 (Currently amended): The method of Claim 22, wherein the  $\alpha$ -dystroglycan fragment is an a fragment of approximately 60 kD fragment.

Claims 25 – 28 (Canceled).

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Claim 29 (Currently amended): The method of claim 22, wherein said tumor cell is an epithelial cell tumor.

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Claim 30 (Currently amended): The method of claim 29, wherein said epithelial cell tumor is a breast epithelial cell tumor.